

REHM  
Appl. No. 10/525,955  
December 5, 2008

### **REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 59, 60, 64, 72-74, 76-79, 85, 88-95, 97, 100 and 101 are in the case.

#### **I. THE INTERVIEW**

At the outset, the undersigned wishes to thank the Examiner (Mr. Meah) and his supervisor (Mr. Nashed) for kindly agreeing to conduct an interview in this case. The interview was conducted on October 23, 2008 and was attended by Mr. Anton Gibson, a representative of the applicant, as well as by the undersigned. The courtesies extended by the Examiner and his supervisor were most appreciated.

In order to facilitate discussion, a proposed set of amended claims was presented to the Examiners. These claims were discussed during the interview. As reflected by the Interview Summary, the Examiners indicated that if the amendments discussed during the interview were effected, the outstanding rejections under 35 U.S.C. §112, and 35 U.S.C. §103 should be overcome. The Examiners also advised, as reflected by the Interview Summary, that if no further prior art is developed during the customary updating search, the claims would be considered for allowance.

#### **II. THE 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION**

Claims 59, 64, 72-79, 81-84, 86-88, 91-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims have

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been amended without prejudice in response to this rejection. The following comments are offered.

Claim 75 has been objected to in view of the expression "a lipid layer". In response, and without conceding to the rejection, claim 75 has been canceled without prejudice.

Claims 59 and 99 have been objected to in view of the recitation "biologically active". In response, and without conceding to the rejection, claim 99 has been canceled without prejudice and the language "biologically active" does not appear in claim 59 as amended. Withdrawal of the formal rejection is now respectfully requested.

### **III. THE 35 U.S.C. §112, FIRST PARAGRAPH, REJECTIONS**

Claims 59-64, 72-79, 81-84, 86-88, 91-95 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In addition, Claims 59, 64, 72-79, 81-84, 86-88, 91-95 stand rejected under 35 U.S.C. §112, first paragraph, on alleged lack of enablement grounds. The rejections are respectfully traversed.

In response, and without conceding to the rejection, the claims have been amended as discussed during the interview. Based on the present description, it is clear that the invention as claimed is described in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, and that the specification is enabling with

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regard to the claim scope as now presented. Withdrawal of the written description and lack of enablement rejections is accordingly respectfully requested.

#### **IV. THE OBVIOUSNESS REJECTIONS**

Claims 59, 64, 72-75 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Madison *et al.* (Microbiol. Mol. Biol. rev 1999, vol. 63, pp 21-53) (Madison) or Steinbuchel *et al.* (US 6,022,729) (Steinbuchel). The rejections are respectfully traversed.

As discussed during the interview, Madison describes PHA biosynthetic pathways and methods for recombinant production of PHA. However, Madison does not suggest production of fusion proteins constructed using proteins involved in PHA synthesis, and does not suggest separation of polymer particles from cultivated cells to produce a composition comprising polyhydroxy carboxylate particles having surface-bound proteins. Madison does not suggest the invention as now claimed, and clearly does not give rise to a *prima facie* case of obviousness.

Steinbuchel is likewise irrelevant. Steinbuchel describes a gene encoding a polyhydroxy alkanoate granule-associated protein designated GA14. Steinbuchel also reports that two C-terminal domains of ten and nine hydrophobic or amphiphilic amino acids respectively are responsible for anchoring GA14 in the phospholipid monolayer of PHA particles (see column 4, lines 13 to 19), and further indicates the use of those domains to produce fusion proteins (see column 4, lines 19 to 21 and column 16, line 48 to column 19, line 23). However, there is no suggestion in Steinbuchel of polymer synthase proteins to produce a composition of polyhydroxy carboxylate particles having

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surface-bound proteins wherein the surface-bound proteins include a fusion protein comprising polymer synthase and a binding domain or biologically active protein or both, as now claimed. Moreover, Steinbuchel does not report that GA14 activity can be retained when GA14 is incorporated in a fusion protein. Steinbuchel likewise fails to give rise to a *prima facie* case of obviousness of the invention as claimed.

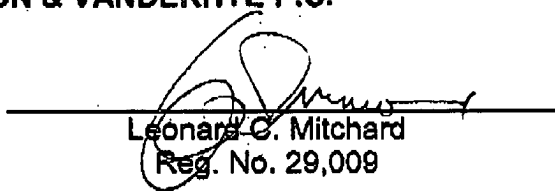
In light of the above, it is believed that the obviousness rejections should be withdrawn. Such action is respectfully requested.

Favorable action is awaited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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Attachments: RCE; one month extension; IDS with attached reference to Yuan *et al.*